FILED
MAY 9 1997
OFFICE OF THE CLERK

No. 96-1611

In The

Supreme Court of the United States

October Term, 1996

COLLAGEN CORPORATION,

Petitioner,

v.

ARLENE FIORE, et al.,

Respondents.

Petition For Writ Of Certiorari
To The Arizona Court Of Appeals, Division One

RESPONDENTS' BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether 21 U.S.C. Sec. 360k(a) preempts respondents' state tort law claims against petitioner manufacturer to recover for injuries caused by a PMA-approved Class III medical device.

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STATEMENT OF THE CASE

Respondents Arlene and Richard Fiore respectfully request that this Court deny the petition for writ of certiorari filed by petitioner Collagen Corporation, which seeks review of the Arizona Court of Appeals opinion in this case. The Arizona Court of Appeals opinion is reported at 930 P.2d 477; the order of the Arizona Supreme Court denying petitioner's petition for review was entered on January 14, 1997.

Certain facts set out by Collagen Corporation in its petition are incorrect, misleading and/or incomplete in the following respects.

1. Any assertion by Collagen Corporation that its Class III device Zyderm was approved under the FDA's regulations appearing at 21 C.F.R. Sec. 814.20, et seq., is incorrect. The PMA for Zyderm was approved in 1981 (Pet. 4). C.F.R. regulations for pre-market applications were not promulgated by the FDA until 1986, five years *after* approval of the Zyderm PMA.

2. Petitioner Collagen Corporation's assertion that it cannot modify Zyderm's packaging or warnings without prior FDA approval is false. Petitioner only *partially* cited the FDA's "conditions of approval" for Zyderm, stating that petitioner cannot make any packaging or labeling changes without FDA approval. (Pet. 5). In truth, those portions of the conditions of approval *omitted* by petitioner in its petition unequivocally allow Collagen to make packaging and labeling warning modifications *without* prior FDA approval where such changes would enhance consumer safety, as the FDA's own regulations

provide. *See* 21 C.F.R. 814.39(d)(2)(i)-(iv). Collagen Corporation's hands were not tied in the event it wanted to warn consumers and physicians of autoimmune risks and injuries regarding Zyderm.

3. The FDA had *not* in 1991 "reviewed Zyderm's record and reconfirmed in its initial finding of safety and effectiveness," as alleged by petitioner (Pet. 5). Rather, in response to a congressional investigation involving Collagen Corporation, the FDA re-reviewed the *original* 1980 PMA materials submitted by petitioner for Zyderm, and determined that under 1980 standards, the PMA had been properly approved. Such a finding does not in any way act to rehabilitate what Collagen Corporation has done since 1981, nor absolve Collagen of any fraud claims.

REASONS WHY THE PETITION SHOULD BE DENIED

Petitioner Collagen Corporation seeks review on three grounds, none of which is convincing.

First, petitioner asserts that plenary review should be granted because of an alleged difference in approach taken by the Pennsylvania Supreme Court in *Green v. Dolsky and Collagen Corporation*, 685 A.2d 110 (1996), cert. denied (No. 96-1340, April 14, 1997), and by the Arizona court below. However, as Collagen acknowledges, Collagen sought certiorari in *Green* on this same basis, and this Court has since denied review in *Green*.[1] Indeed, Collagen effectively concedes (Pet. 8) that review should

[1] This Court denied the petition in *Green*, No. 96-1340, on April 14, 1997.

not be granted here in *Fiore* if the petition in *Green* is denied. Thus, plenary review should be denied under Collagen's own assertions.

Second, Collagen asks that the petition be granted, vacated and remanded in light of this Court's decision in *Medtronic v. Lohr*, 518 U.S. ___, 116 S. Ct. 2240 (1996). Collagen argues that, under *Medtronic*, the MDA preempts respondents' tort claims involving Zyderm because it underwent the FDA pre-market approval ("PMA") process. *Medtronic*, however, does not state, or even imply, such a result, and particularly, would not do so in regards to respondent's causes of action, as here shown:

First, the majority opinion in *Medtronic* indicates that a duty-to-warn claim, such as that alleged here by respondents, is not preempted in PMA cases because FDA regulations do not bar manufacturers of PMA devices from providing stronger and different warnings to protect consumer safety. 116 S. Ct. 2256 n. 16. As to respondent's manufacturing-defect claim, the very same federal regulations that were held not to have preemptive effect in *Medtronic* are applicable to the manufacturer of PMA devices, such as the injectable collagen device at issue here. *Medtronic* at 2256-58. *See* 21 C.F.R. Part 820.

Furthermore, regarding respondents' design-defect claims, although the PMA process may be more scientifically "rigorous" (that is, complex) than the 510(k) process, a PMA nonetheless does not require that a device be designed in a particular manner, but only that the manufacturer comply with its own manufacturing specifications set out in the PMA. Thus, the PMA is not a "specific" preemption-triggering requirement, which is a

prerequisite for preemption under *Medtronic*. *Id.* at 2258 (no preemption under the MDA where there is no "specific mandate on manufacturers or producers").

With respect to respondents' claim that petitioner Collagen defrauded the FDA, physicians, and the general public concerning the true characteristics of the device, there is no preemption of such a claim, since it is based on a general state-law duty not to deceive, and not on specific state-law requirements that would interfere with federal regulatory objectives. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); *Medtronic*, 116 S. Ct. at 2257-58. In any event, *Medtronic* did not address preemption of fraud claims, and therefore provides no basis for remanding this case for further consideration.

Lastly, Collagen seeks a remand on the basis of the Ninth Circuit's decision in *Papike v. Tambrands, Inc.*, 107 F.3d 737 (1997). Although the rationale of *Papike* differed from that of the Ninth Circuit's no-preemption ruling in *Kennedy v. Collagen Corporation*, 67 F.3d 1453, *cert. denied*, 116 S. Ct. 2579 (1996), neither the rationale nor the result of *Papike* bears on the decision below. *Papike* did not even involve a PMA device, but rather a Class II tampon, which is subject to specific, regulatory label warnings mandated by the FDA. The plaintiff in *Papike* alleged that she contracted toxic shock syndrome due to the manufacturer's failure to warn on proper use of the product, arguing that the manufacturer should have given a warning over and above the specific, detailed tampon warnings mandated by the FDA at 21 C.F.R. Sec. 801.430.

Unlike in *Papike*, no specific, mandated federal regulations of that sort are present here, and the PMA

approval process, like the 510(k) process at issue in *Medtronic*, is entirely generic and non-specific. In sum, although *Papike* leaves open a small window in the Ninth Circuit for preemption of damages claims where the FDA has acted by regulation with great specificity, it says nothing about the claims at issue here and thus provides no basis for remand.[2]

Moreover, Collagen Corporation is incorrect in postulating that the holding in *Kennedy* has been modified by *Lohr*. It is true that in *Papike*, the Ninth Circuit retracted its earlier *Kennedy* statement that the MDA cannot preempt state tort claims. Collagen Corporation, however, is erroneously expanding a retraction of the generalized statement into a retraction of the *Kennedy* holding. Nothing in *Papike* or *Lohr* negates the *holding* in *Kennedy* or *Fiore*, which is that the plaintiffs' claims are not preempted by the general PMA process. The Ninth Circuit's application of the MDA preemption did not change in *Papike*, nor was it changed by *Lohr*.

Neither *Lohr* nor *Papike* require or even suggest that the Arizona Court of Appeals decision was wrongly decided. The petition for writ of certiorari should be denied.

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[2] This Court's decision to seek the views of the U.S. Solicitor General in another MDA preemption case, *Iolab v. Hunter*, No. 96-1126 (Order dated April 21, 1997), has no bearing here. *Iolab* involves an investigational device (IDE), not a PMA device. Indeed, as noted above, this Court denied certiorari in a PMA case, *Green v. Dolsky and Collagen Corporation*, No. 96-1340, just a week before seeking the Solicitor General's views in *Iolab*.

CONCLUSION

Respondents Arlene and Richard Fiore respectfully request that writ of certiorari be denied.

Respectfully submitted,

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